

Substitute Form PTO-1449

U.S. Department of Commerce  
Patent and Trademark Office

Attorney's Docket No.

Application No.

17023-030001

10/715,876

## Information Disclosure Statement

by Applicant

(Use several sheets if necessary)

Applicant

Jerrold P. Weiss et al.

Filing Date

November 17, 2003

Group Art Unit

1654

(37 CFR 1.98(b))

## U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
<i>[Signature]</i>	AA	3,561,444	02/09/71	Boucher			
<i>[Signature]</i>	AB	3,703,173	11/21/72	Dixon			
<i>[Signature]</i>	AC	4,624,251	11/25/86	Miller			
<i>[Signature]</i>	AD	4,635,627	01/13/87	Gam			
<i>[Signature]</i>	AE	4,962,091	10/09/90	Eppstein et al.			

## Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
<i>[Signature]</i>	AF	WO 94/07529	04/14/94	PCT				
<i>[Signature]</i>	AG	WO 97/19688	06/05/97	PCT				

## Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
<i>[Signature]</i>	AH	Abreu et al., "TLR4 and MD-2 Expression Is Regulated by Immune-mediated Signals in Human Intestinal Epithelial Cells," <i>J. Biol. Chem.</i> , 2002, 277(23):20431-20437
<i>[Signature]</i>	AI	Abreu et al., "Decreased Expression of Toll-Like Receptor-4 and MD-2 Correlates with Intestinal Epithelial Cell Protection Against Dysregulated Proinflammatory Gene Expression in Response to Bacterial Lipopolysaccharide," <i>J. Immunol.</i> , 2001, 167:1609-1617
<i>[Signature]</i>	AJ	Akashi et al., "Lipopolysaccharide Interaction with Cell Surface Toll-like Receptor 4-MD-2: Higher Affinity than That with MD-2 or CD14," <i>J. Exp. Med.</i> , 2003, 198(7):1035-1042
<i>[Signature]</i>	AK	Akashi et al., "Cutting Edge: Cell Surface Expression and Lipopolysaccharide Signaling Via the Toll-Like Receptor 4-MD-2 Complex on Mouse Peritoneal Macrophages," <i>J. Immunol.</i> , 2000, 164:3471-3475
<i>[Signature]</i>	AL	Altschul et al., "Basic Local Alignment Search Tool," <i>J. Mol. Biol.</i> , 1990, 215:403-410
<i>[Signature]</i>	AM	Altschul et al., "Gapped BLAST and PSI-BLAST: a new generation of protein database search programs," <i>Nucl. Acids Res.</i> , 1997, 25(17):3389-3402
<i>[Signature]</i>	AN	Anderson et al., "A simple method for the rapid generation of recombinant adenovirus vectors," <i>Gene Ther.</i> , 2000, 7:1034-1038
<i>[Signature]</i>	AO	Anderson, "Toll signaling pathways in the innate immune response," <i>Curr. Opin. Immunol.</i> , 2000, 12:13-19
<i>[Signature]</i>	AP	Arbour et al., "TLR4 mutations are associated with endotoxin hyporesponsiveness in humans," <i>Nat. Genet.</i> , 2000, 25:187-191
<i>[Signature]</i>	AQ	Bacchi et al., "Polyamine metabolism in the Microsporidia," <i>Biochemical Society Transactions</i> , 2003, 31(2):420-423
<i>[Signature]</i>	AR	Bals et al., "Human $\beta$ -Defensin 2 Is a Salt-sensitive Peptide Antibiotic Expressed in Human Lung," <i>J. Clin. Invest.</i> , 1998, 102(5):874-880



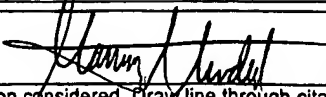
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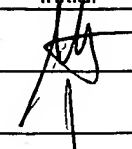
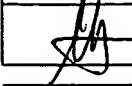
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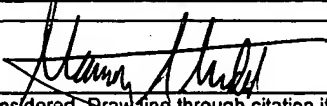
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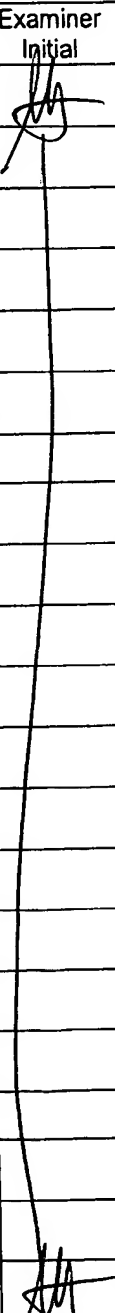
Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	AS	Bandi et al., "Nontypeable <i>Haemophilus influenzae</i> in the Lower Respiratory Tract of Patients with Chronic Bronchitis," <u>Am. J. Respir. Crit. Care Med.</u> , 2001, 164:2114-2119
	AT	Becker et al., "CD14-dependent Lipopolysaccharide-induced $\beta$ -Defensin-2 Expression in Human Tracheobronchial Epithelium," <u>J. Biol. Chem.</u> , 2000, 275(38):29731-29736
	AU	Beutler and Poltorak, "Sepsis and evolution of the innate immune response," <u>Crit. Care Med.</u> , 2001, 29(7)(Suppl.):S2-S7
	AV	Beutler and Rietschel, "Innate immune sensing and its roots: the story of endotoxin," <u>Nat. Rev. Immunol.</u> , 2003, 3:169-176
	AW	Bustin "Absolute quantification of mRNA using real-time reverse transcription polymerase chain reaction assays," <u>J. Mol. Endocrinol.</u> , 2000, 25:169-193
	AX	Corpet, "Multiple sequence alignment with hierarchical clustering," <u>Nucl. Acids Res.</u> , 1988, 16(22):10881-10890
	AY	Correia et al., "Lipopolysaccharide Is in Close Proximity to Each of the Proteins in Its Membrane Receptor Complex," <u>J. Biol. Chem.</u> , 2001, 276(24):21129-21135
	AZ	Denning et al., "Pseudomonas Pyocyanin Increases Interleukin-8 Expression by Human Airway Epithelial Cells," <u>Infect. Immun.</u> , 1998, 66(12):5777-5784
	AAA	Douwes et al., "Biological agents - recognition," <u>Modern Industrial Hygiene</u> , Vol. 2, 2003, J.L. Perkins (ed.), ACGIH, Cincinnati, pp. 219-292
	ABB	Frick et al., " <i>Haemophilus influenzae</i> Stimulates ICAM-1 Expression on Respiratory Epithelial Cells," <u>J. Immunol.</u> , 2000, 164:4185-4196
	ACC	Ganz, "Antimicrobial polypeptides in host defense of the respiratory tract," <u>J. Clin. Invest.</u> , 2002, 109:693-697
	ADD	García et al., "Human $\beta$ -defensin 4: a novel inducible peptide with a specific salt-sensitive spectrum of antimicrobial activity," <u>FASEB J.</u> , 2001, 15:1819-1821
	AEE	Giardina et al., "Construction of Acetate Auxotrophs of <i>Neisseria meningitidis</i> to Study Host-Meningococcal Endotoxin Interactions," <u>J. Biol. Chem.</u> , 2001, 276(8):5883-5891
	AFF	Gioannini et al., "Isolation of an endotoxin-MD-2 complex that produces Toll-like receptor 4-dependent cell activation at picomolar concentrations," <u>Proc. Natl. Acad. Sci. USA</u> , 2004, 101(12):4186-4191
	AGG	Gioannini et al., "An Essential Role for Albumin in the Interaction of Endotoxin with Lipopolysaccharide-binding Protein and sCD14 and Resultant Cell Activation," <u>J. Biol. Chem.</u> , 2002, 277(49):47818-47825
	AHH	Gioannini et al., "Regulation of interactions with endotoxin with host cells," <u>J. Endotoxin Res.</u> , 2003, 9(6):401-408
	AII	Gottar et al., "The <i>Drosophila</i> immune response against Gram-negative bacteria is mediated by a peptidoglycan recognition protein," <u>Nature</u> , 2002, 416:640-644
	AJJ	Hailman et al., "Lipopolysaccharide (LPS)-binding Protein Accelerates the Binding of LPS to CD14," <u>J. Exp. Med.</u> , 1994, 179:269-277
	AKK	Harder et al., "Mucoid <i>Pseudomonas aeruginosa</i> , TNF- $\alpha$ , and IL-1 $\beta$ , but Not IL-6, Induce Human $\beta$ -Defensin-2 in Respiratory Epithelia," <u>Am. J. Respir. Cell Mol. Biol.</u> , 2000, 22:714-721
	ALL	Harder et al., "Isolation and Characterization of Human $\beta$ -Defensin-3, a Novel Human Inducible Peptide Antibiotic," <u>J. Biol. Chem.</u> , 2001, 276(8):5707-5713
	AMM	Harder et al., "A peptide antibiotic from human skin," <u>Nature</u> , 1997, 387:861
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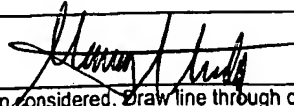
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	ANN	Higgins and Sharp, "Fast and sensitive multiple sequence alignments on a microcomputer," <u>CABIOS</u> , 1989, 5(2):151-153
	AOO	Higgins and Sharp, "CLUSTAL: a package for performing multiple sequence alignment on a microcomputer," <u>Gene</u> , 1988, 73:237-244
	APP	Hoffman et al., "Phylogenetic Perspectives in Innate Immunity," <u>Science</u> , 1999, 284:1313-1318
	AQQ	Huang et al., "Parallelization of a local similarity algorithm," <u>CABIOS</u> , 1992, 8(2):155-165
	ARR	Inzana et al., "Phase Variation and Conservation of Lipooligosaccharide Epitopes in <i>Haemophilus somnus</i> ," <u>Infect. Immun.</u> , 1997, 65(11):4675-4681
	ASS	Iovine et al., "The Carboxyl-terminal Domain of Closely Related Endotoxin-binding Proteins Determines the Target of Protein-Lipopolysaccharide Complexes," <u>J. Biol. Chem.</u> , 2002, 277(10):7970-7978
	ATT	Janeway Jr. and Medzhitov, "Innate Immune Recognition," <u>Annu. Rev. Immunol.</u> , 2002, 20:197-216
	AUU	Jia et al., "Discovery of new human $\beta$ -defensins using a genomics-based approach," <u>Gene</u> , 2001, 263:211-218
	AVV	Jia et al., "Endotoxin responsiveness of human airway epithelia is limited by low expression of MD-2," <u>Am. J. Physiol. Lung Cell Mol. Physiol.</u> , 2004, 287:L428-L437
	AWW	Jiang et al., "Cutting Edge: Lipopolysaccharide Induces Physical Proximity Between CD14 and Toll-Like Receptor 4 (TLR4) Prior to Nuclear Translocation of NF- $\kappa$ B," <u>J. Immunol.</u> , 2000, 165:3541-3544
	AXX	Karlin and Altschul, "Methods for assessing the statistical significance of molecular sequence features by using general scoring schemes," <u>Proc. Natl. Acad. Sci. USA</u> , 1990, 87:2264-2268
	AYY	Karlin and Altschul, "Applications and statistics for multiple high-scoring segments in molecular sequences," <u>Proc. Natl. Acad. Sci. USA</u> , 1993, 90:5873-5877
	AZZ	Karp et al., "An In Vitro Model of Differentiated Human Airway Epithelia," <u>Meth. Mol. Biol.</u> , 2002, 188:115-137
	AAAA	Kawasaki et al., "Involvement of TLR4/MD-2 complex in species-specific lipopolysaccharide-mimetic signal transduction by Taxol," <u>J. Endotoxin Res.</u> , 2001, 7(3):232-236
	ABBB	Kawasaki et al., "Identification of Mouse MD-2 Residues Important for Forming the Cell Surface TLR4-MD-2 Complex Recognized by Anti-TLR4-MD-2 Antibodies, and for Conferring LPS and Taxol Responsiveness on Mouse TLR4 by Alanine-Scanning Mutagenesis," <u>J. Immunol.</u> , 2003, 170:413-420
	ACCC	Lamping et al., "LPS-binding Protein Protects Mice from Septic Shock Caused by LPS or Gram-negative Bacteria," <u>J. Clin. Invest.</u> , 1998, 101(10):2065-2071
	ADDD	Latz et al., "Lipopolysaccharide Rapidly Traffics to and from the Golgi Apparatus with the Toll-like Receptor 4-MD-2-CD14 Complex in a Process That Is Distinct from the Initiation of Signal Transduction," <u>J. Biol. Chem.</u> , 2002, 277(49):47834-47843
	AEEE	Lehninger, "The amino acid building blocks of proteins," <u>Biochemistry</u> , 1975, 2 <sup>nd</sup> ed., pp. 73-75
	AFFF	Lemaitre et al., "The Dorsoventral Regulatory gene Cassette <i>spätzle/Toll/Cactus</i> Controls the Potent Antifungal Response in <i>Drosophila</i> Adults," <u>Cell</u> , 1996, 86:973-983
	AGGG	Lerman et al., "Nasopharyngeal Carriage of Antibiotic-Resistant <i>Haemophilus influenzae</i> in Healthy Children," <u>Pediatrics</u> , 1979, 64(3):287-291


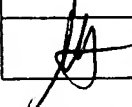
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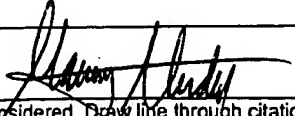
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	AHHH	Liu et al., "Structure and mapping of the human $\beta$ -defensin HBD-2 gene and its expression at sites of inflammation," <u>Gene</u> , 1998, 222:237-244
	AIII	Malley et al., "Recognition of pneumolysin by Toll-like receptor 4 confers resistance to pneumococcal infection," <u>Proc. Natl. Acad. Sci. USA</u> , 2003, 100(4):1966-1971
	AJJJ	Mathews et al., "Production of $\beta$ -Defensin Antimicrobial Peptides by the Oral Mucosa and Salivary Glands," <u>Infect. Immun.</u> , 1999, 67(6):2740-2745
	AKKK	McCray, Jr. and Bentley, "Human Airway Epithelia Express a $\beta$ -defensin," <u>Am. J. Respir. Cell Mol. Biol.</u> , 1997, 16:343-349
	ALLL	McCray, Jr. et al., "Alveolar Macrophages Inhibit Retrovirus-Mediated Gene Transfer to Airway Epithelia," <u>Hum. Gene Ther.</u> , 1997, 8:1087-1093
	AMMM	McNamara et al., "Ocular Surface Epithelia Express mRNA for Human Beta Defensin-2," <u>Exp. Eye Res.</u> , 1999, 69:483-490
	ANNN	Means et al., "The biology of Toll-like receptors," <u>Cytokine Growth Factor Rev.</u> , 2000, 11:219-232
	AOOO	Medzhitov and Janeway, Jr., "An ancient system of host defense," <u>Curr. Opin. Immunol.</u> , 1998, 10:12-15
	APPP	Medzhitov and Janeway, Jr., "Innate immune recognition: mechanisms and pathways," <u>Immunol. Rev.</u> , 2000, 173:89-97
	AQQQ	Medzhitov et al., "A human homologue of the <i>Drosophila</i> Toll protein signals activation of adaptive immunity," <u>Nature</u> , 1997, 388:394-397
	ARRR	Meinkoth and Wahl, "Hybridization of Nucleic Acids Immobilized on Solid Supports," <u>Anal. Biochem.</u> , 1984, 138:267-284
	ASSS	Miyake, "Innate recognition of lipopolysaccharide by CD14 and toll-like receptor 4-MD-2: unique roles for MD-2," <u>Int. Immunopharmacol.</u> , 2003, 3:119-128
	ATTT	Mueller-Anneling et al., "Ambient Endotoxin Concentrations in PM <sub>10</sub> from Southern California," <u>Environ. Health Pers.</u> , 2004, 112(5):583-588
	AUUU	Mullen et al., "The role of disulfide bonds in the assembly and function of MD-2," <u>Proc. Natl. Acad. Sci. USA</u> , 2003, 100(7):3919-3924
	AVVV	Munford et al., "Biosynthetic radiolabeling of bacterial lipopolysaccharide to high specific activity," <u>J. Immunol. Meth.</u> , 1992, 148:115-120
	AWWW	Muroi et al., "MD-2, a Novel Accessory Molecule, Is Involved in Species-Specific Actions of <i>Salmonella</i> Lipid A," <u>Infect. Immun.</u> , 2002, 70(7):3546-3550
	AXXX	Muroi et al., "Regions of the Mouse CD14 Molecule Required for Toll-like Receptor 2- and 4-mediated Activation of NF- $\kappa$ B," <u>J. Biol. Chem.</u> , 2002, 277(44):42372-42379
	AYYY	Myers and Miller, "Optimal alignments in linear space," <u>CABIOS</u> , 1988, 4(1):11-17
	AZZZ	Nagai et al., "Essential role of MD-2 in LPS responsiveness and TLR4 distribution," <u>Nat. Immunol.</u> , 2002, 3(7):667-672
	AAAAA	Needleman and Wunsch, "A General Method Applicable to the Search for Similarities in the Amino Acid Sequence of Two Proteins," <u>J. Mol. Biol.</u> , 1970, 48:443-453
	ABBBB	Newman, "Therapeutic aerosols," <u>Aerosols and the Lung</u> , 1984, Clarke and Pavia (eds.), pp. 197-224, Butterworths, London, England


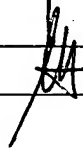
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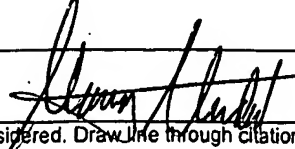
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	ACCCC	Ohnishi et al., "N-Linked Glycosylations at Asn <sup>26</sup> and Asn <sup>114</sup> of Human MD-2 Are Required for Toll-Like Receptor 4-Mediated Activation of NF- $\kappa$ B by Lipopolysaccharide," <u>J. Immunol.</u> , 2001, 167:3354-3359
	ADDDD	O'Neil et al., "Expression and Regulation of the Human $\beta$ -Defensins hBD-1 and hBD-2 in Intestinal Epithelium," <u>J. Immunol.</u> , 1999, 163:6718-6724
	AEEEE	Pearson and Lipman, "Improved tools for biological sequence comparison," <u>Proc. Natl. Acad. Sci. USA</u> , 1988, 85:2444-2448
	AFFFF	Pearson et al., "Using the FASTA Program to Search Protein and DNA Sequence Databases," <u>Meth. Mol. Biol.</u> , 1994, 24:307-331
	AGGGG	Re and Strominger, "Monomeric Recombinant MD-2 Binds Toll-like Receptor 4 Tightly and Confers Lipopolysaccharide Responsiveness," <u>J. Biol. Chem.</u> , 2002, 277(26):23427-23432
	AHHHH	Re and Strominger, "Separate Functional Domains of Human MD-2 Mediate Toll-Like Receptor 4-Binding and Lipopolysaccharide Responsiveness," <u>J. Immunol.</u> , 2003, 171:5272-5276
	AIIII	Reynolds, "Integrated Host Defense Against Infections," <u>The Lung: Scientific Foundations</u> , 1997, Crystal et al. (eds.), Raven Press, Ltd., New York, NY, pp. 2353-2365
	AJJJJ	Schröder and Harder, "Human beta-defensin-2," <u>Int. J. Biochem. Cell Biol.</u> , 1999, 31:645-651
	AKKKK	Schromm et al., "Molecular Genetic Analysis of an Endotoxin Nonresponder Mutant Cell Line: A Point Mutation in a Conserved Region of MD-2 Abolishes Endotoxin-induced Signaling," <u>J. Exp. Med.</u> , 2001, 194(1):79-88
	ALLLL	Schütt, "Molecules in focus: CD14," <u>Int. J. Biochem. Cell Biol.</u> , 1999, 31:545-549
	AMMMM	Schutte and McCray, Jr., " $\beta$ -Defensins in Lung Host Defense," <u>Annu. Rev. Physiol.</u> , 2002, 64:709-748
	ANNNN	Schutte et al., "Discovery of five conserved $\beta$ -defensin gene clusters using a computational search strategy," <u>Proc. Natl. Acad. Sci. USA</u> , 2002, 99(4):2129-2133
	AOOOO	Shimazu et al., "MD-2, a Molecule that Confers Lipopolysaccharide Responsiveness on Toll-like Receptor 4," <u>J. Exp. Med.</u> , 1999, 189(11):1777-1782
	APPPP	Singh et al., "Production of $\beta$ -defensins by human airway epithelia," <u>Proc. Natl. Acad. Sci. USA</u> , 1998, 95:14961-14966
	AQQQQ	Smith et al., "Endobronchial Infection in Cystic Fibrosis," <u>Acta Paediatr. Scand. Suppl.</u> , 1989, 363:31-36
	ARRRR	Smith and Waterman, "Comparison of Biosequences," <u>Adv. Appl. Math.</u> , 1981, 2:482-489
	ASSSS	Stryer, "Conformation and Dynamics," <u>Biochemistry</u> , 2 <sup>nd</sup> edition, W.H. Freeman and Co., San Francisco, 1981, pp. 14-15
	ATTTT	Takeda and Akira, "Toll receptors and pathogen resistance," <u>Cell. Microbiol.</u> , 2003, 5(3):143-153
	AUUUU	Tapping and Tobias, "Cellular Binding of Soluble CD14 Requires Lipopolysaccharide (LPS) and LPS-binding Protein," <u>J. Biol. Chem.</u> , 1997, 272(37):23157-23164
	AVVVV	Tauszig et al., "Toll-related receptors and the control of antimicrobial peptide expression in <i>Drosophila</i> ," <u>Proc. Natl. Acad. Sci. USA</u> , 2000, 97(19):10520-10525
	AWWWW	Thomas et al., "Evidence of a trimolecular complex involving LPS, LPS binding protein and soluble C14 as an effector of LPS response," <u>FEBS Lett.</u> , 2002, 531:184-188

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	AXXXX	Tsutsumi-Ishii and Nagaoka, "Modulation of Human $\beta$ -Defensin-2 Transcription in Pulmonary Epithelial Cells by Lipopolysaccharide-Stimulated Mononuclear Phagocytes Via Proinflammatory Cytokine Production," <u>J. Immunol.</u> , 2003, 170:4226-4236
	AYYYY	Ulevitch and Tobias, "Recognition of Gram-negative bacteria and endotoxin by the innate immune system," <u>Curr. Opin. Immunol.</u> , 1999, 11:19-22
	AZZZZ	Ulevitch, "Molecular Mechanisms of Innate Immunity," <u>Immunol. Res.</u> , 2000, 21(2):49-54
	AAAAAA	Viriyakosol et al., "MD-2 Binds to Bacterial Lipopolysaccharide," <u>J. Biol. Chem.</u> , 2001, 276(41):38044-38051
	ABBBBB	Visintin et al., "Lysines 128 and 132 Enable LPS Binding to MD-2, Leading to Toll-like Receptor 4 Aggregation and Signal Transduction," <u>J. Biol. Chem.</u> , 2003, 278(48):48313-48320
	ACCCCC	Visintin et al., "Secreted MD-2 is a large polymeric protein that efficiently confers lipopolysaccharide sensitivity to Toll-like receptor 4," <u>Proc. Natl. Acad. Sci. USA</u> , 2001, 98(21):12156-12161
	ADDDDD	Wang et al., "Increasing Epithelial Junction Permeability Enhances Gene Transfer to Airway Epithelia <i>In Vivo</i> ," <u>Am. J. Respir. Cell Mol. Biol.</u> , 2000, 22:129-138
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Examiner Signature 	Date Considered 07/05
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